Serial Number: 10/613,633 Filing Date: July 3, 2003

Title: WATER-SOLUBLE GLOBULIN CONCENTRATE FOR IMPROVING GROWTH IN ANIMALS

REMARKS

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This responds to the Office Action mailed on May 2, 2005, and the documents cited therewith.

Claim 9, 20, and 21 are amended, claim 19 is canceled, and no claims are added; as a result, claims 9-18, 20, and 21 are now pending in this application. Claims 9 and 21 have been amended to recite that the source of the globulin concentrate is animal plasma. Support for this change appears, for example, at page 13, second complete paragraph of Applicants' specification. In addition, claims 9 and 21 have been amended to recite that the globulin concentrate is administered at any stage of the animal's life. Support for this change appears, for example, at page 16, last paragraph of Applicants' specification. Claim 19 has been cancelled. The dependency of claim 20 has been changed from cancelled claim 19 to claim 9. The specification has been amended to be consistent with original claim 15. No new matter has been added.

Information Disclosure Statement

The Examiner indicated that the foreign patents and non-patent literature have not been considered as Applicants failed to provide the copies of the references.

Pursuant to 37 C.F.R. §1.98(d), copies of the documents were not provided as these references were previously cited by or submitted to the U.S. Patent and Trademark Office in connection with Applicants' prior U.S. application, Serial No. 09/659,103, filed on September 11, 2000, which is relied upon for an earlier filing date under 35 U.S.C. §120.

Personal Interview Summary

Applicants thank Examiners Kim and Nolan for the courtesy of a personal interview on October 4, 2005 with Applicants' representative Richard A. Schwartz.

Applicants' representative pointed out that the source of the composition of US Patent 4,096,244 is blood serum, while Applicants may use blood plasma as an immunoglobulin source.

The Examiners suggested that making claim 9 independent and incorporating the elements of claim 19 into claim 9 would overcome the § 102(b) rejection over US Patent 4,096,244.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in her next communication so that Applicants can amend or supplement the interview summary.

Claim Objections

Claims 10-21 were objected to because claims 10-21 fail to use a proper article "the" and "administered" in claim 20.

Applicants request clarification of the Examiner's objection. Cancellation of claim 19 and the fact that claim 20 now depends upon claim 9 may obviate this objection.

Claim 15 was objected to under 37 C.F.R. § 1.75(d) as failing to provide proper antecedent basis for the claimed subject matter.

The Examiner asserted that claim 15 recites *about* while the specification at page 16, line 9 recites *approximately*. Applicants have amended the specification at page 16 to recite *about* and thereby to provide antecedent basis for the term. Withdrawal of this objection is respectfully requested.

§112 Rejections of the Claims

Claims 9-21 were rejected under 35 U.S.C. § 112 as being indefinite for dependence upon a non-elected claim. This rejection is respectfully traversed.

Applicants submit that the claims were definite as filed, and they cannot be made indefinite and subject to a rejection for indefiniteness as a result of a practice of the Office, namely a restriction requirement. Nevertheless, Applicants have amended the claims to remove any recitation of claim 1 from the pending claims. Withdrawal of this rejection is respectfully requested.

Claims 14 and 15 were rejected under 35 U.S.C. § 112, second paragraph, as being in improper dependent form for failing to further limit the subject matter of a previous claim. This rejection is respectfully traversed.

The Examiner asserted that the recitation of 0.1% by weight in claim 15 broadens claim 14. Office Action at page 2. The Examiner is reminded that the globulin concentrate is not

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comprised exclusively of IgG. Therefore, it is possible that the percentage by weight of IgG may be lower than the recited weight percentage range for the globulin concentrate. Withdrawal of this rejection is respectfully requested.

§102 Rejection of the Claims

Claims 9-21 were rejected under 35 U.S.C. § 102(b) for anticipation by Newson et al. (U.S. Patent No. 4,096,244). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. In re Arkley, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." Del Mar Engineering Lab v. Physio-Tronics, Inc., 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); In re Oelrich, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The Examiner asserted that "Newson et al. teach a use of blood-derived immunoglobulin in a supplement for a piglet" and that "Newson et al. further teach the serum is pooled from swine or cattle." Office action at page 3 (citations omitted)(emphasis added). As the Examiner recognized, the source of the composition of Newson et al. is blood serum and not blood plasma as in the present claims. Therefore, the composition of Newson et al. is not identical to

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Applicants' composition, and the Examiner has not established that the respective compositions are in fact identical. As such, there can be no anticipation.

Furthermore, Newson *et al.* is silent with respect to improving the animals' weight gain and growth, which is Applicants' claimed method of use. The Examiner asserted that improving weight gain would be an inherent result of administering the composition of Newson *et al.* because the patient population of Newson *et al.* is identical to that of Applicants' claims. However, the present claims recite that Applicants' supplement may be administered at any stage of the animal's life, while Newson *et al.* appears to be restricted to newborn piglets. Thus, the patient populations are <u>not</u> identical. In addition, for the Examiner's argument to have any merit at all, the composition administered in Newson *et al.* would have to be identical to that of Applicants. Because the sources of Applicants' supplement and that of Newson *et al.* are different, the compositions are not necessarily identical (see above), and the Examiner has not supplied the factual and technical grounds to establish that the respective compositions are in fact identical. As such, there is no anticipation or inherency. Withdrawal of this rejection is respectfully requested.

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CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (703)239-9592 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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